Lipocine Announces Financial Results for the Second Quarter Ended June 30, 2021

SALT LAKE CITY, Aug. 5, 2021 /PRNewswire/ -- Lipocine Inc. (NASDAQ: LPCN), a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders, today announced financial results for the second quarter ended June 30, 2021, and provided a corporate update.

Recent Corporate Highlights

- Announced positive topline results from the Phase 2 *LiFT* ("Liver Fat intervention with oral Testosterone") clinical study, investigating LPCN 1144 in biopsy-confirmed NASH male subjects
- 36-week biopsy data from the *LiFT* clinical study are expected in August 2021
- Continued enrolling patients into an open label extension to the *LiFT* clinical study in which all patients will have access to LPCN 1144
- Clinical data from the *LiFT* clinical study were presented at The International Liver Congress™ 2021, the annual meeting of the European Association for the Study of the Liver ("EASL"), Digital Event, which took place June 23-26, 2021
    - Results from the *LiFT* clinical study showed that LPCN 1144 treatment significantly reduced liver fat and key liver injury markers in biopsy confirmed NASH subjects
    - Data from the *LiFT* clinical study showed high prevalence of low normal or overtly hypogonadal levels of testosterone in histologically established NASH subjects
    - LPCN 1144 was shown to improve body composition in biopsy-confirmed NASH patients
- The U.S. Food and Drug Administration ("FDA") cleared the Company's Investigational New Drug Application ("IND") to initiate a Phase 2 study to evaluate the therapeutic potential of LPCN 1154, an oral neuro-steroid product candidate, for the treatment of postpartum depression ("PPD") in adults
    - Top-line results from an ongoing pharmacokinetic ("PK") study to assess dose proportionality are expected in the third quarter of 2021
    - Following the PK study, a proof-of-concept study to evaluate the safety, tolerability, and efficacy of LPCN 1154 in adult female subjects diagnosed with PPD is expected to begin in the fourth quarter of 2021
- Entered into a global settlement agreement with Clarus Therapeutics Inc. ("Clarus") to resolve all outstanding claims in the on-going intellectual property litigation between Lipocine and Clarus, as well as the on-going interference proceeding between the two companies
- Continued business development activities surrounding TLANDO related to the commercialization of TLANDO upon approval by the FDA
- Expect the first subject will be dosed in the proof-of-concept Phase 2 study in male cirrhotic subjects to evaluate the therapeutic potential of LPCN 1148 for the management of cirrhotic subjects in the fourth quarter of 2021

Second Quarter Ended June 30, 2021 Financial Results
Lipocine reported a net loss of $6.8 million, or ($0.08) per diluted share, for the second quarter ended June 30, 2021, compared with a net loss of $6.4 million, or ($0.13) per diluted share, for the second quarter ended June 30, 2020.

Research and development expenses were $1.5 million for the second quarter ended June 30 2021, compared with $2.3 million for the second quarter ended June 30, 2020. The decrease was primarily due to a decrease in contract research organization expense and outside consulting costs related to the LPCN 1144 Phase 2 *LiFT* clinical study in NASH subjects, a decrease in costs associated with TLANDO and a decrease in personnel expense, which was mainly due to a decrease in stock compensation and bonus expense. These decreases were offset by an increase in costs related to LPCN 1154 and LPCN 1107, as well as increases in other R&D expenses.

General and administrative expenses were $1.5 million for the second quarter ended June 30, 2021, compared with $2.0 million for the second quarter ended June 30, 2020. The decrease in general and administrative was primarily related to a decrease in personnel costs, which was mainly due to a decrease in stock compensation and bonus expense, and a decrease in legal expenses. These decreases were offset by increases in corporate insurance and other general and administrative expenses.

As of June 30, 2021, the Company had $46.6 million of unrestricted cash, cash equivalents, and marketable investments, compared to $19.7 million of unrestricted cash, cash equivalents and marketable investment securities as of December 31, 2020.

Six Months Ended June 30, 2021 Financial Results
Lipocine reported a net loss of $10.2 million, or ($0.12) per diluted share, for the six months ended June 30, 2021, compared with a net loss of $12.1 million, or ($0.27) per diluted share, for the six months ended June 30, 2020.

Research and development expenses were $3.0 million for the six months ended June 30, 2021, compared with $4.8 million for the six months ended June 30, 2020. The decrease in research and development expenses was primarily due to a decrease in contract research organization expense and outside consulting costs related to the LPCN 1144 Phase 2 *LiFT* clinical study in NASH subjects, a decrease in costs associated with TLANDO and a net decrease in personnel expense, which was mainly due to a decrease in stock compensation expense offset by increases in salaries. These decreases were offset by an increase in costs related to LPCN 1154 and LPCN 1107, as well as increases in other R&D expenses.

General and administrative expenses were $3.1 million for the six months ended June 30, 2021, compared with $4.0 million for the six months ended June 30, 2020. The decrease in general and administrative expenses was primarily due to a decrease in legal costs and a decrease in personnel costs, mainly due a reduction in stock compensation expense. These decreases were offset by an increase in corporate insurance expenses and an increase in other general and administrative expenses.

About Lipocine Inc.
Lipocine Inc. is a clinical-stage biopharmaceutical company focused on metabolic and endocrine disorders using its proprietary drug delivery technologies. Lipocine's clinical development pipeline includes: TLANDO, LPCN 1144, TLANDO XR, LPCN 1148, LPCN 1154, and LPCN 1107. TLANDO, a novel oral prodrug of testosterone containing testosterone undecanoate, has received tentative approval from the FDA for conditions associated with a deficiency of endogenous testosterone, also known as hypogonadism, in adult males. LPCN 1144, an oral prodrug of bioidentical testosterone, recently completed a proof-of-concept clinical study demonstrating the potential utility in the treatment of non-cirrhotic NASH. LPCN 1144 is currently being studied in a Phase 2 clinical study. TLANDO XR, a novel oral prodrug of testosterone, originated and is being developed by Lipocine as a next-generation oral testosterone product with potential for once-daily dosing. In a phase 2 clinical evaluation when administered as once daily or twice daily TLANDO XR met the typical primary and secondary end points. LPCN 1148 is an oral prodrug of bioidentical testosterone targeted for the treatment of cirrhosis. LPCN 1154 is an oral neuro-steroid targeted for the treatment of post-partum depression. LPCN 1107 is potentially the first oral hydroxyprogesterone caproate product candidate indicated for the prevention of recurrent preterm birth and has been granted orphan drug designation by the FDA. For more information, please visit www.lipocine.com.

Forward-Looking Statements
This release contains "forward-looking statements" that are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995 and include statements that are not historical facts regarding Lipocine's product candidates and related clinical trials, the timing of completion of clinical trials, the potential uses and benefits of our product candidates, and our product development efforts. Investors are cautioned that all such forward-looking statements involve risks and uncertainties, including, without limitation, the risks that the FDA will not approve any of our products, risks

related to our products, expected product benefits not being realized, clinical and regulatory expectations and plans not being realized, new regulatory developments and requirements, risks related to the FDA approval process including the receipt of regulatory approvals, the results and timing of clinical trials, patient acceptance of Lipocine's products, the manufacturing and commercialization of Lipocine's products, and other risks detailed in Lipocine's filings with the SEC, including, without limitation, its Form 10-K and other reports on Forms 8-K and 10-Q, all of which can be obtained on the SEC website at www.sec.gov. Lipocine assumes no obligation to update or revise publicly any forward-looking statements contained in this release, except as required by law.

LIPOCINE INC. AND SUBSIDIARIES
Condensed Consolidated Balance Sheets
(Unaudited)

	June 30, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 10,967,713	$ 19,217,382
Restricted cash	-	5,000,000
Marketable investment securities	35,672,059	449,992
Accrued interest income	232,568	391
Prepaid and other current assets	283,180	661,258
Total current assets	47,155,520	25,329,023
Other assets	23,753	23,753
Total assets	$ 47,179,273	$ 25,352,776
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 906,476	$ 1,597,220
Accrued expenses	1,444,188	1,653,178
Debt - current portion	3,957,627	3,333,333
Litigation settlement liability - current portion	2,500,000	-
Total current liabilities	8,808,291	6,583,731
Debt - non-current portion	-	2,257,075
Warrant liability	1,125,429	1,170,051
Litigation settlement liability - non-current portion	1,500,000	-
Total liabilities	11,433,720	10,010,857
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value $0.0001 per share, 10,000,000 shares authorized; zero issued and outstanding	-	-
Common stock, par value $0.0001 per share, 100,000,000 shares authorized; 88,296,360 and 70,041,967 issued and 88,290,650 and 70,036,257 outstanding	8,830	7,005
Additional paid-in capital	217,986,752	187,407,634
Treasury stock at cost, 5,710 shares	(40,712)	(40,712)
Accumulated other comprehensive loss	(186)	-
Accumulated deficit	(182,209,131)	(172,032,008)
Total stockholders' equity	35,745,553	15,341,919
Total liabilities and stockholders' equity	$ 47,179,273	$ 25,352,776

LIPOCINE INC. AND SUBSIDIARIES
Condensed Consolidated Statements of Operations and Comprehensive Loss
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2021	2020	2021	2020
Operating expenses:				
Research and development	$ 1,464,687	$ 2,268,984	$ 3,045,228	$ 4,780,739
General and administrative	1,525,592	1,953,535	3,059,544	4,038,795
Total operating expenses	2,990,279	4,222,519	6,104,772	8,819,534
Operating loss	(2,990,279)	(4,222,519)	(6,104,772)	(8,819,534)
Other income (expense):				
Interest and investment income	17,344	7,177	27,993	67,115

Interest expense	(57,428)	(87,847)	(126,401)	(221,192)
Unrealized gain (loss) on warrant liability	221,322	(2,066,445)	28,257	(3,166,474)
Litigation settlement	(4,000,000)	-	(4,000,000)	-
Total other expense, net	(3,818,762)	(2,147,115)	(4,072,151)	(3,320,551)
Loss before income tax expense	(6,809,041)	(6,369,634)	(10,176,923)	(12,140,085)
Income tax expense	-	-	(200)	(200)
Net loss	$ (6,809,041)	$ (6,369,634)	$ (10,177,123)	$ (12,140,285)
Basic loss per share attributable to common stock	$ (0.08)	$ (0.13)	$ (0.12)	$ (0.27)
Weighted average common shares outstanding, basic	88,290,650	49,769,253	85,556,110	45,558,442
Diluted loss per share attributable to common stock	$ (0.08)	$ (0.13)	$ (0.12)	$ (0.27)
Weighted average common shares outstanding, diluted	88,290,650	49,769,253	85,556,110	45,558,442
Comprehensive loss:				
Net loss	$ (6,809,041)	$ (6,369,634)	$ (10,177,123)	$ (12,140,285)
Net unrealized gain (loss) on available-for-sale securities	22,273	(104)	(186)	(66)
Comprehensive loss	$ (6,786,768)	$ (6,369,738)	$ (10,177,309)	$ (12,140,351)

SOURCE Lipocine Inc.

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